

Claims

1. Process for the expansions of TALL lymphocytes expansion, wherein at least 1×10^9 cells are grown in a homogeneous culture system.
2. The process as claimed in claim 1, wherein said homogeneous system is a
5 cell-factory.
3. The process as claimed in claim 2, wherein the expansion in the homogeneous system is preceded by a process of pre – expansion in flask until obtaining a number of cells from 0.7 to 1×10^6 .
4. The process as claimed in claim 3, wherein the cellular density of the inoculum
10 is at least 0.7×10^6 cells/ml and is preferably equal to 0.75×10^6 cells/ml and, at the harvest time, the density is lower than 2×10^6 cells/ml, preferably than 1×10^6 .
5. The process as claimed in claim 2, wherein the cell-factory is a 10-chamber unit.
- 15 6. The process as claimed in claim 1, wherein TALL lymphocytes are selected from the group consisting of: TALL-104, TALL-107, TALL-103/2 cell lines, optionally genetically modified.
7. Process according to claim 6 wherein TALL are TALL-104 lymphocytes.
8. The process as claimed in any of claims 1 to 7, wherein the complete culture
20 medium in the cell-factory amplification phase also comprises 10% max human serum, preferably in the range of 4 to 6%, still more preferably of 5%, optionally foetal serum in a concentration of 0 to 10% and interleukin in a concentration of 100/IU.
9. The process as claimed in claim 8, wherein interleukin-2 is added to the cell
25 culture every 48-90 hrs.
10. The process as claimed in claim 8, wherein the cell growth in the homogeneous system takes place in an antibiotic-free culture medium.
11. Process for the preparation of frozen bags of TALL lymphocytes in an amount of at least 1×10^9 cells, characterized in the fact it comprises the process
30 according to claims 1 - 10.
12. Process as claimed in claim 11, wherein the bag is sealed transversally to the bag filling collet at least in two points to create at least a sampling chamber

containing a cell culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.

13. Process for the preparation of a therapeutic dose of at least 1×10^9 TALL lymphocytes in a homogeneous culture, wherein said lymphocytes are
- 5 characterised by a $CD3^+$ and $CD8^+$ immunologic markers expression of 98% min, preferably $\geq 99\%$, and by the $CD56^+$ marker expression of 95% at least, preferably $\geq 97\%$.
14. The process as claimed in claim 13, wherein the lymphocytes are TALL-104.
15. The process as claimed in claim 13, wherein said lymphocytes are
- 10 characterised by a biological activity, determined by a cytotoxicity assay on appropriate target cells, equal to at least 70% of the control.
16. TALL lymphocytes obtainable according to the process of claims 1 – 10.